PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2008/000509	15.04.2008	19.04.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/053

Applicant
CHEETAH MEDICAL LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	see form PCT/ISA/210	Knüpling, Moritz Telephone No. +31 70 340-2891

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2008/000509

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 2-4,9-20* (claims 2, 3, 9-20 only partially)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 2-4,9-20* (claims 2, 3, 9-20 only partially)

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-20*
	No: Claims	
Inventive step (IS)	Yes: Claims	1-20 *
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-20 * (*claims 2, 3, 9-20 only if not dependent on claim 2)
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Claim 2 relates to a method of predicting the onset of electromechanical dissociation which is practised on the human or animal body. This method is considered as a diagnostic method which falls under Rule 67.1 (iv) PCT. Claims 3, 4, 9 - 20 if dependent on claim 20 equally define a diagnostic method. Therefore, no written opinion about novelty, inventive step or industrial applicability will be given (Article 34(4) (a) (I) PCT) for these claim combinations.

Re Item V.

1 Reference is made to the following documents:

D1 : TCHOUDOVSKI I ET AL: "New approach in developing of the algorithms for resuscitation assistance" CONFERENCE PROCEEDINGS. 26TH ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY (IEEE CAT. NO.04CH37558) IEEE PISCATAWAY, NJ, USA, vol. 2, 2004, pages 956-959 Vol.2, XP002495751 ISBN: 0-7803-8439-3

D2 : EP 1 247 487 A (OSYPKA MEDICAL GMBH [DE]) 9 October 2002 (2002-10-09)

D3: WO 00/66222 A (INTERMEDICS INC [US]) 9 November 2000 (2000-11-09)

2 Document D3 discloses a method of predicting electromechanical dissociation (EMD) in a heart of a subject. Further, D3 discloses determining electrical activity of the heart based on an electrocardiac signal (p. 6, l. 19, 20) and determining a blood flow measure (p. 7, l. 1 - 3).

3 Document D1 discloses a method of predicting EMD or pulseless electrical activity (PEA) in a heart of a subject (D1, passage bridging p. 956 and 957). Further, D1

discloses determining electrical activity of the heart based on an electrocardiac signal (p. 957, first col., l 16 from bottom) and determining a blood flow measure ('alteration of blood volume with time'; p. 958, col. 2, first full sentence).

4 Both D1 and D3 fail to disclose extracting from a composite signal an electrocardiac signal and extracting from said composite signal a radiofrequency signal.

According to D3 EMD is detected if an ECG is present and no adequate blood flow is detected (D3, p. 9, l. 6 - 11). Thus, D3 fails to disclose detection of onset of EMD. According to D3, a condition is diagnosed where the heart is already in EMD.

D1 fails to disclose the step of predicting the onset of EMD if the blood flow measure is below a predetermined threshold and the electrical activity is above a predetermined threshold. Rather, According to D1, PEA is detected if the ejection ratio is under a threshold (p. 958, second col., point 3.).

5 The subject-matter of claim 1 is therefore novel (Article 33(2) PCT)

6 The problem to be solved by the present invention may be regarded as providing a simple and reliable system for detecting onset of EMD.

7 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

From D2 it is known to extracting from a composite signal an electrocardiac signal and extracting from a composite signal a radiofrequency signal (para. [0037]. Further, since D2 relates to the measurement of the same or corresponding parameters of the heart as D1 or D3, the man skilled in the art would have no difficulty to include those features into a device already known from D1 or D3.

8 D2, however, fails to disclose detection of onset of EMD. Since this feature is neithr disclosed nor rendered obvious by the prior art, method according to claim 1 involves

an inventive step (Article 33(3) PCT).

9 For the same reasons, mutatis mutandis, the subject-matter of claim 5 is new and involves an inventive step (Articles 33(2), 33(3) PCT).